



**Patient package insert according to Pharmacists' Regulations (Preparations) – 1986**

This medicine can be sold with a physician's prescription only

**Detrusitol® SR 2 mg**

Each slow release capsule contains:

Tolterodine L-tartrate 2 mg

**Detrusitol® SR 4 mg**

Each slow release capsule contains:

Tolterodine L-tartrate 4 mg

Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine"

**Read this entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar to yours.

**1. What is the medicine intended for?**

For the treatment of overactive bladder with symptoms of urinary frequency, urgency and/or urge incontinence.

**Therapeutic group:** Muscarinic receptor antagonist.

**2. Before using the medicine**

**Do not use the medicine if:**

- You are hypersensitive (allergic) to the active ingredient, or to any of the other ingredients this medicine contains (see section 6).
- You have difficulties emptying the urinary bladder (also called "urinary retention").
- Your stomach is emptying slowly (also called "gastric retention").
- You have an eye problem called "uncontrolled narrow angle glaucoma".
- You are hypersensitive to medicines containing the substance fesoterodine.

**Special warnings regarding the use of the medicine**

**Before the treatment with Detrusitol SR, tell the doctor if:**

- You have a gastric problem or digestive problems.
- You have a difficulty emptying your urinary bladder or you have weak urine flow.
- You have an eye problem called "narrow angle glaucoma".
- You have liver problems.
- You have kidney problems.
- You suffer from a disease called myasthenia gravis.
- You or any of your family members have a rare heart problem called "QT interval prolongation" (prolonged QT syndrome).

- You are pregnant or breastfeeding, planning to become pregnant or to breastfeed - see section "Pregnancy and breastfeeding".

### **Children and adolescents**

There is no information regarding the effectiveness of using this preparation in children and adolescents.

### **Drug interactions**

**If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.**

Other medicines may affect how your body handles **Detrusitol SR**. Your doctor may prescribe a lower dose if you are taking:

- Certain medicines for fungal infections such as ketoconazole, itraconazole, miconazole.
- Certain medicines for bacterial infections such as clarithromycin.
- Certain medicines for treatment of HIV infection such as ritonavir, saquinavir, atazanavir.

You should know the medicines you take. Keep the list of medicines with you to show the doctor or pharmacist each time you get a new medicine.

### **Use of the medicine and food**

You can take the capsule with or without food.

### **Pregnancy, breastfeeding and fertility**

If you are pregnant, think you may be pregnant or are planning to become pregnant, consult the doctor before taking this medicine. It is not known whether **Detrusitol SR** may harm your fetus.

If you are breastfeeding or are planning to breastfeed, consult the doctor before taking this medicine. It is not known whether **Detrusitol SR** passes into breast milk and whether it may harm the baby.

### **Driving and using machines**

Do not drive, operate machines or perform other dangerous activities until you know how **Detrusitol SR** affects you. Anti-muscarinic medicines, such as **Detrusitol SR**, may cause side effects such as blurred vision, dizziness or drowsiness.

### **Important information about some of the ingredients of the medicine**

The capsule contains sucrose – if you have been told by the doctor that you have an intolerance to some sugars, consult the doctor before starting the treatment.

## **3. How to use the medicine?**

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only. Do not change the dosage unless you have been instructed to do so by your doctor.

The usual recommended dosage is:

One capsule once a day with a glass of water. Swallow the whole capsule since this is a mechanism of slow release. Tell the doctor if you cannot swallow capsules.

You can take the capsule with or without food.  
Take the capsule at the same time every day.

**Do not exceed the recommended dose.**

**If you have accidentally taken a higher dosage**

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

**If you forgot to take the medicine**

If you forgot to take this medicine at the designated time, take the next dose on the following day. Do not take 2 doses of the medicine at the same day.

Continue with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop taking this medicine without consulting the doctor.

**Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.**

**If you have further questions on the use of this medicine, consult the doctor or pharmacist.**

**4. Side effects**

Like any medicine, the use of **Detrusitol SR** may cause side effects in some users. Do not be alarmed when reading the list of side effects, you may not suffer from any of them.

**Stop taking Detrusitol SR and seek medical help immediately if you experience the following symptoms:**

**Detrusitol SR** may cause allergic reactions that may be serious. Symptoms of a serious allergic reaction may include swelling of the face, lips, throat or tongue, difficulty breathing, upper respiratory tract obstruction or a drop in blood pressure.

**The most common side effects are:**

- Dry mouth
- Headache
- Constipation
- Abdominal pain

**Additional side effects:**

Dizziness, indigestion, tiredness, dry eye, blurred vision, sleepiness, anxiety, sinusitis, pain upon urination.

Severe allergic reaction (anaphylaxis) and subcutaneous edema, rapid heartbeats (tachycardia), strong heartbeats (palpitations), peripheral edema (edema in the legs), diarrhea, confusion, disorientation, memory impairment, hallucinations.

Reports of exacerbation of dementia symptoms (e.g., confusion, disorientation, delusions) have been obtained after **Detrusitol SR** treatment was initiated in patients taking cholinesterase inhibitors for the treatment of dementia.

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

## **5. How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (Exp. date) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.

## **6. Additional information**

**In addition to the active ingredient, the medicine also contains:**

Sugar spheres, ethylcellulose, hydroxypropyl methylcellulose, medium chain triglycerides, oleic acid, ammonium hydroxide, purified water, gelatin, yellow iron oxide, titanium dioxide and FD&C Blue #2.

Each **Detrusitol SR 2 mg** capsule contains 67.23 mg sugar.

Each **Detrusitol SR 4 mg** capsule contains 134.5 mg sugar.

**What the medicine looks like and what the package contains:**

**Detrusitol SR 2 mg** - a blue-green capsule with white printed text.

**Detrusitol SR 4 mg** - a blue capsule with white printed text.

Approved package sizes:

Blister package: 28 capsules

Bottle package: 28 capsules

Not all package sizes may be marketed.

**Drug registration numbers at the national drug registry of the Ministry of Health:**

**Detrusitol SR 2 mg:** 125-56-30466

**Detrusitol SR 4 mg:** 125-55-30467

Revised in February 2025 according to MOH guidelines.

**Manufacturer and registration holder:**

Dexcel Ltd, 1 Dexcel street, Or Akiva 3060000, Israel.